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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,433	02/12/2007	Colin Dickens	16873-55310	6573

24728 7590 04/14/2009

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EXAMINER	
STUART, COLIN W	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,433	DICKENS ET AL.	
	Examiner	Art Unit	
	COLIN STUART	4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "aerosol means" and "delivery stations" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 22-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The language regarding the gas flow as "non-turbulent" in claims 1, 17, 19-20, 22, and 24-25 lacks enablement because the examiner cannot ascertain how to make the device based on the specification and drawings without having turbulent flow. Fig. 5 specifically shows curved surfaces which would cause turbulence.

Claims 2-16, 18, 23, and 26-32 are rejected based on dependency on a rejected claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11, 14-15, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the inlet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "the particles" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim element “means for cooperating” in claim 9 line 2 is a means plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material or acts for the claimed function. The only mention of cooperation in the disclosure is the passage "a guide arranged to cooperate with the nose” pg. 5 ln. 2 and the following claims 10 and 11 appear to define the means for cooperating as being a plurality of outer nozzles.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means plus function limitation under 25 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

Claims 10-11 and 15 are rejected based on dependency on a rejected claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 14-17, 19, 21-22, 24-25, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Djupesland (7,481,218).

In regards to claim 1, Djupesland teaches a nasal device which includes a delivery means having an outlet (outlet of nozzle 35; Fig. 3) and support means (31) which support the delivery means with outlet at a predetermined location in the nostril at a substantially stable and non-turbulent flow.

In regards to claim 2, Djupesland's nasal device which is arranged such that the inhalation flow into the nostril is unimpeded (see Fig. 3).

In regards to claim 3, Djupesland's nasal device has a port (61) to the atmosphere through which a gas flow travels towards and surrounds the outlet of nozzle 35 (see Fig. 3).

In regards to claim 4, Djupesland teaches a nasal device which includes a guide (25) which guide the support means (31) into a position with predetermined orientation with respect to the nostril.

In regards to claim 5, Djupesland teaches a nasal device with delivery means which includes a delivery nozzle (35).

In regards to claims 6 and 14, Djupesland teaches a nasal device with support means which includes an outer nozzle (37). The inlet of the delivery nozzle (35) is within the outer nozzle, and the outlet is adjacent the outlet of the outer nozzle (37) (see Fig. 3).

In regards to claim 7, Djupesland teaches a nasal device in which the outer nozzle is arranged to fit within the nostril (see Fig. 6(a)) and perpendicular to the direction of the flow which is entering port (61).

In regards to claim 15, Djupesland teaches a nasal device which includes a housing (43) for containing particles of active material, and a delivering passage (51) which communicates with the delivery nozzle (35).

In regards to claims 16 and 19, Djupesland teaches a nasal device which includes an aerosol means (55) which is also the particle propulsion means. Element 55 of Djupesland's reference is a piston that provides the particles of active material into a mist ejected from outlet of delivery nozzle (35) in a substantially non-turbulent flow.

In regards to claim 17, Djupesland teaches a nasal device which includes a gas propulsion means (61) which is a port to the atmosphere creating a pressure difference which causes air to be propelled into nostril at a substantially non-turbulent flow.

In regards to claim 21, Djupesland teaches a nasal device which includes a guide (25) which cooperates with the nose as discussed above along with a pair of delivery stations (31) corresponding with each nostril and a substance delivery means (35) positioned at both delivery stations.

In regards to claims 22 and 30, Djupesland teaches a nasal delivery device whose use involves a method of delivering active material to a region of the nasal passage or olfactory region from a predetermined location in the nostril in a substantially non-turbulent flow. The predetermined location for delivery is adjacent to the tip of the nose (see Fig. 6(a)).

In regards to claims 24 and 25, the method of use of Djupesland's nasal device includes providing the non-turbulent flow into the nasal passage (see Fig. 6(a)). The predetermined location for the delivery material is the outlet of the delivery nozzle (35) and is surrounded by the substantially non-turbulent gas flow through the outer nozzle (37).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 8-11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (7,481,218) as applied to claim 4 above, and further in view of Kirsch et al. (6,763,832).

In regards to claim 8, Djupesland teaches a nasal delivery device including an outer nozzle (Djupesland 37) as discussed above but is silent as to providing an abutment means mounted on the outer nozzle for abutting the outlet of the nostril. However, Kirsch teaches a nasal cannula which includes an abutment means (Kirsch 31b) mounted on an outer nozzle of the cannula which abuts the outlet of the nostrils when in use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the outer nozzle of Djupesland to include the abutment means (Kirsch 31b) as taught b Kirsch in order to provide a more comfortable and proper fit.

In regards to claim 9, Djupesland teaches a nasal delivery device with a guide which includes means for cooperating with the other nostrils in the form of the spacers on the front side of the guide (Djupesland 25). The spacing between the two outer nozzles (Djupesland 37) cooperate with the other nostril and provide proper dimensioning for both outer nozzles (Djupesland 37) to be inserted into the nostrils.

In regards to claim 10, the modified Djupesland's reference includes a plurality of outer nozzles (Djupesland 37) and the abutment means includes a base (32b) on which the rest of the outer nozzles are mounted.

In regards to claim 11, the modified Djupesland's reference teaches support means including outer nozzles (Djupesland 37) as discussed above.

In regards to claim 23, Djupesland's method of use for the nasal device teaches delivering the particles in the nasal passage however is silent as to delivery at a velocity substantially matching the gas flow. Kirsch teaches a nasal cannula which includes a

gas source (Kirsch 100) and a gas flow regulator (Kirsch 70) which allows for the ability to control the flow of gas through the cannula. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Djupesland's device to include gas source (Kirsch 100) flow regulator (Kirsch 70) and tubing (Kirsch 50) connected to the port (Djupesland 61) to control the gas flow to match the delivery of the particles in order to ensure an optimal mix of particles with the gas flow.

7. Claims 12-13, 20, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (7,481,218) as applied to claims 4 or 19 or 22 above, and further in view of Wood (2002/0092527).

In regards to claim 12, the Djupesland's reference teaches all the limitations but is silent as to providing that the support means are movable with respect to the guide between positions corresponding to each nostril respectively. However, Wood teaches a nasal cannula which includes that the "nasal inserts 30, are preferably made from silicone elastomer" (Wood para. 0047 ln. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the outer nozzles (Djupesland 37) of Djupesland to be made of the silicone elastomer as taught by Wood in order to provide an adjustable and more comfortable fit with the user.

In regards to claim 13, the modified Djupesland's reference teaches a nasal device in which the guide (Djupesland 25) includes a member (Djupesland 69) arranged to cooperate with the nose such that the device may be positioned in only one

orientation. The member (Djupesland 69) is a mouthpiece which aligns the outer nozzles (Djupesland 37) to each nostril respectively in one orientation only.

In regards to claim 20, Djupesland teaches a nasal device with particle propulsion means as discussed above however is silent as to providing the delivery gas flow having a velocity of about +/- 20%. Wood teaches a nasal cannula in which the outlets of the nasal inserts are of dimensions "allowing for generous laminar flow" (Wood para. 0047 ln. 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the outlets of Djupesland's nasal device to take the dimensions to provide laminar, non-turbulent flow as taught by Wood in order to provide a flow path which optimally delivers active material to the entire nasal passages without losing material to vortices present in turbulent flow.

In regards to claims 31 and 32, Djupesland teaches a method of use of the nasal device which includes delivering active material to the turbinate region, which is part of the nasal passages, but is silent as to the predetermined location being closer to the tip of the nose than the base of the nose. However, Wood teaches a nasal cannula which includes that the "nasal inserts 30, are preferably made from silicone elastomer" (Wood para. 0047 ln. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the outer nozzles (Djupesland 37) of Djupesland to be made of the silicone elastomer as taught by Wood in order to provide an adjustable nozzle to target more specific areas of the nasal passages. With the modified elastomer nozzles the predetermined location of delivery is capable of being

adjusted to be in an area closer to the tip than base of the nose or the base than tip of the nose.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (7,481,218) as applied to claim 17 above, and further in view of Kirsch et al. (6,763,832), Hickle (6,938,619), and Strickland et al. (6,679,265).

In regards to claim 18, Djupesland teaches a nasal device which teaches a gas propulsion means but is silent as to the specific rate of the gas flow. However, Kirsch teaches a nasal cannula which includes a gas source (Kirsch 100) and a gas flow regulator (Kirsch 70) which allows for the ability to control the flow of gas through the cannula. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Djupesland's device to include gas source (Kirsch 100) flow regulator (Kirsch 70) and tubing (Kirsch 50) connected to the port (Djupesland 61) to control the rate of gas flow through the device for varying delivery times. Both Kirsch and Djupesland are silent to a specific value range of the gas flow rate, however 1 litre/min to 30 litres/min are well-known to the art of ventilation through the nasal cavity. Furthermore, Hickle discloses a flow rate of "2.0 to 15.0 liters per minute" (Hickle col. 6 ln. 63) and Strickland discloses a flow rate of "about 10 to 50 liters/minutes" (Strickland claim 2 ln. 2). The modified Djupesland nasal device with the gas flow regulator and source is capable of producing flow rates at these ranges.

9. Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (7,481,218) as applied to claim 22 above, and further in view of Djupesland (WO 02/068029).

In regards to claim 26-29, Djupesland ('218) teaches a method of use of the nasal device which includes providing particles of materials in an aerosolized form however is silent as to the exact aerodynamic diameter ranges of the particles. Djupesland ('029) teaches a nasal device in which the optimal mean particle size is about 10 μm to about 30 μm and a specialized mechanical pump which can generate particle diameter size down to 5 μm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the aerosolizing means of Djupesland ('218) with the aerosolizing means of Djupesland ('029) in order to provide a fine particle mist to allow for better absorption of the active material into the nasal passage tissue.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Flickinger (5,906,198), Krauser (4,699,136), and Ohki et al. (5,901,703) all relate to nasal delivery devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 4177

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